



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

8/28

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

08/736,267 10/24/96 BACKSTROM K 06275/004001

HM22/0714

EXAMINER

JANIS K FRASER
RISH & RICHARDSON
225 FRANKLIN STREET
BOSTON MA 02110-2804

LUKTON, D

ART UNIT	PAPER NUMBER
----------	--------------

1653

30

DATE MAILED:

07/14/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/736,267

Applicant(s)

Backstrom

Examiner

David Lukton

Group Art Unit

1653

Responsive to communication(s) filed on Apr 21, 2000

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1035 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

Claim(s) 1-10, 12-16, 21, 22, 26-32, 50-97, and 101 is/are pending in the application
Of the above, claim(s) 2, 21, 22, 26-30, 32, and 50-97 is/are withdrawn from consideration
 Claim(s) _____ is/are allowed.
 Claim(s) 1, 3-10, 12-16, 31, and 101 is/are rejected.
 Claim(s) _____ is/are objected to.
 Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
 The drawing(s) filed on _____ is/are objected to by the Examiner.
 The proposed drawing correction, filed on _____ is approved disapproved.
 The specification is objected to by the Examiner.
 The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 All Some* None of the CERTIFIED copies of the priority documents have been
 received.
 received in Application No. (Series Code/Serial Number) _____
 received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892
 Information Disclosure Statement(s), PTO-1449, Paper No(s). 27 & 28
 Interview Summary, PTO-413
 Notice of Draftsperson's Patent Drawing Review, PTO-948
 Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Serial No. 736,267
Art Unit 1653

Claims 1-10, 12-16, 21, 22, 26-32, 50-97, 101 remain pending.

Applicants' election of Group I (claims 1, 3-10, 12-16, 31, 101, examined *in part*) without traverse is acknowledged. Also acknowledged are the species elections (human growth hormone and sodium taurocholate). Claims 2, 21, 22, 26-30, 32, 50-97 are withdrawn from consideration.

*

Claims 1, 3-10, 12, 101 are rejected under 35 U.S.C. §102(e) as being anticipated by Illum (USP 5,707,644).

As indicated previously (Paper No. 24, mailed 4/28/98), Illum teaches a dry composition comprising microparticles that are less than 10 microns in size, which composition also contains peptides and enhancers. In paper No. 26 (filed 11/2/98) applicants traversed by arguing that the instant claims do not encompass the compositions disclosed by Illum because the instant claims require that the composition be non-hygroscopic. However, there is no such exclusion in the claims as currently rendered.

The claims are anticipated.

*

Claims 1, 3-10, 12, 101 are rejected under 35 U.S.C. §102(b) as being anticipated by Durani (WO 91/16882).

The teachings of the reference were indicated previously (Paper No. 24, mailed 4/28/98).

In traversing, (No. 26, filed 11/2/98) applicants argued that the "intended use" of the phospholipids was different than that of applicants themselves. However, this argument, even if true, is not effective to negate the validity of this rejection. If Durani had disclosed that the only purpose of the phospholipids was, e.g., to cure Alzheimer's Disease, with no mention of a physical effect, there would still be anticipation. On the other hand, if there are actually differences in the structures of the phospholipids used by Durani, and those used by applicants, then applicants could introduce limitations into the claims which exclude all phospholipids other than those which have particular structural (and not merely functional) features in question.

The claims are anticipated.

*

Claims 1, 3-10, 12, 101 are rejected under 35 U.S.C. §102(e) as being anticipated by Patton (USP 5,607,915).

Patton teaches (col 3, lines 15-26) dry powder formulations as well as those suitable for propellant dispersion, wherein the particle size is less than 10 microns. Also taught (col 6, line 22+) is the use of surfactants.

In imposing this ground of rejection, the term "dry" in instant claim 1 is interpreted to mean that water is absent, not that chlorofluorocarbons are absent. Moreoever, the claimed composition "consists essentially of" the indicated components. Probably this ground of rejection could be overcome by excluding the presence of solvents normally used

Serial No. 736,267
Art Unit 1653

as propellants. (No determination has been made as to what might or might not constitute new matter).

The claims are anticipated.

*

Claims 1, 3-10, 12-16, 31, 101 are rejected under 35 U.S.C. §103 as being unpatentable over Patton (USP 5,607,915) in view of: (a) Clark (USP 3,911,138) or (b) Poynton (USP 4,920,061) or (c) Ecanow (USP 4,914,084).

Patton teaches (col 3, lines 15-26) dry powder formulations as well as those suitable for propellant dispersion, wherein the particle size is less than 10 microns. Also taught (col 5, line 46+) is the use of "bulking agents" such as albumin. Patton does not characterize albumin as a surfactant. However, each of the secondary references teach that albumin is a surfactant. (Clark: col 8, lines 5-9; Poynton: col 6, line 7; Ecanow: col 5, line 65 to col 6, line 1).

Thus, if the disclosure of Patton is taken in conjunction with that of any of the three secondary references, the claims are rendered obvious.

*

Applicants are requested to point out the page and line number where support for "non-hygroscopic additives" (claim 1) can be found. Alternatively, applicants should cancel the non-elected invention.

Serial No. 736,267
Art Unit 1653

-5-

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton [phone number (703)308-3213].

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



DAVID LUKTON
PATENT EXAMINER
GROUP 1800